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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,882	10/10/2006	Stefan Golz	2004P56028 WOUS	5299

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SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,882	GOLZ ET AL.	
	Examiner	Art Unit	
	SAMUEL W. LIU	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 3/20/06 which amends claims 1-12 and 18-26 has been entered. The following Office action is applied to the pending claims 1-26.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Restriction is required under 35 U.S.C. 121 and 372.

Group I, claims 1 and 4-11, drawn to a method of screening for therapeutic agent comprising contacting a test compound with an AdipoR2 polypeptide and detecting binding of said compound to said polypeptide.

Group II, claims 2-3, drawn to a method of screening for therapeutic agent comprising determining the activity of AdipoR2 polypeptide in the presence of a test compound.

Group III, claims 12-17, drawn to a method of screening for therapeutic agent comprising contacting a test compound with an AdioR2 polynucleotide and detecting binding of said compound to said polynucleotide.

Group IV, claim 18, drawn to a method of diagnosing a disease state in a mammal comprising determining a amount of an AdioR2 polynucleotide in healthy or/and diseased mammal (*in vivo* diagnosis).

Group V, claims 19-21, drawn to a pharmaceutical composition comprising a therapeutic agent, e.g., RNA, antisense oligonucleotide, polypeptide, antibody ribozyme, and a small (organic or inorganic) molecule, which binds to the AdipoR2 polypeptide or regulates the activity thereof.

Group VI, claim 22, drawn to a pharmaceutical composition comprising an AdipoR2 polynucleotide.

Group VII, claim 23, drawn to a pharmaceutical composition comprising an AdipoR2 polypeptide.

Group VIII, claims 24 and 26, drawn to a method of treating a disease state such as cardiovascular disease, or a method of regulating of AdipoR2 polypeptide activity in a mammal comprising administering to said mammal a regulator (the therapeutic agent) of the AdioR2 polypeptide (see the note below).

Group IX, claims 24 and 26, drawn to a method of treating a disease state such as cardiovascular disease, or a method of regulating of AdipoR2 polynucleotide activity in a mammal comprising administering to said mammal a regulator (the therapeutic agent) of the AdioR2 polynucleotide (see the note below).

***Note** that claim 24 sets forth "regulator of AdipoR2"; for patent examination purpose, the phrase "AdipoR2" herein is taken to encompass "AdpoR2 polynucleotide" and "AdipoR2 polypeptide". Since the regulator for the "AdipoR2 polynucleotide" and the regulator for "AdipoR2 polypeptide" are considered be patentably regulatory molecule each other molecule, the restriction requirement for claim 24 herein is proper (see above Groups VIII and IX).

Group X, claim 25, drawn to a method of preparing a pharmaceutical composition comprising the regulator (the therapeutic agent) of AdioR2 polypeptide comprising determining whether said regulator which ahs been identified ameliorates the symptoms of a disease, and formulating said regulator determined thereof with a pharmaceutically acceptable carrier (see the note below).

Group XI, claim 25, drawn to a method of preparing a pharmaceutical composition comprising the regulator (the therapeutic agent) of AdioR2 polynucleotide comprising determining whether said regulator which ahs been identified ameliorates the symptoms of a disease, and formulating said regulator determined thereof with a pharmaceutically acceptable carrier (see the note below).

***Note** that claim 25 sets forth "pharmaceutical composition" without recites the composition comprising the "regulator of AdipoR2" (see claim 25, step i). For patent examination purpose, the phrase "AdipoR2" herein is taken to encompass "AdpoR2 polynucleotide" and "AdipoR2 polypeptide". Since the regulator for the "AdipoR2 polynucleotide" and the regulator for "AdipoR2 polypeptide" are considered be patentably distinct regulatory molecule each other, the restriction requirement for claim 25 herein is proper (see above Groups X and XI).

The inventions listed as Groups I-XI do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The claimed AdipoR2 polypeptide and polynucleotide encoding the polypeptide thereof, the pharmaceutical composition comprising polypeptide or polypeptide thereof, and claimed methods using said AdipoR2 polypeptide or polynucleotide are obvious over Wu et al. (US 7435808 B2). Wu et al. teach (i) polynucleotide encoding an AdipoR2 polypeptide (col. 4, lines 42-47); (ii) isolated polypeptide thereof (col. 4, lines 65-68) and the pharmaceutical composition comprising said polypeptide or polynucleotide (col. 142, lines 45-66); (ii) a process of diagnosing pathological condition (disease) comprising determining amount of expression said polypeptide (col. 6, lines 53-61); (iv) a method of identifying/screening for a teats compound (a binding partner or agonist or antagonist compound thereof, or a compound capable of modulating bioactivity of an AdipoR2 protein) comprising determining whether the AdipoR2 polypeptide is capable of binding to the compound (col. 6, lines 62-67, and col. 9, line 25 to col. 11, line 55); and (v) a method of treating a disease such as cardiovascular disease (col. 7, lines 30-59). Thus, the claimed adipoR2 product, composition, and methods of using said product or composition do not constitute a special technical feature as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Applicants are advised that reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Additional Election Under 35 USC 121

Applicants are further required under 35 US 121 (1) to elect a single therapeutic agent to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

[1] If Group V is elected, applicants are required to elect one type of therapeutic agent, e.g., an RNA, an antisense oligonucleotide, a polypeptide, an antibody, a ribozyme, or a small molecule) from claim 21 because the above-mentioned agent molecules are distinct from one another in chemical structure and biological function, and are capable of separate manufacture or use.

[2]] If any one of Groups VIII, IX, X and XI is elected, applicants are required to elect one disease state from claims 24 and 26 (Group VIII and Group IX) and claim 25 (Group X and Group XI) because the disease states set forth in the claims have distinct/ different patient populations and treatment schedules, e.g., cardiovascular disease versus urological disease.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 US 121 since chemical structure and properties as well as bioactivity of RNA, polypeptide, antibody, and ribosome which set forth in claim 12 of Group V are patentably distinct from one another, and since the disease states recited in claims 24 and 26 such as cardiovascular disease, urological disease, hematological disease, respiratory disease, gastroenterological disease and cancer have distinct/different patient populations, treatment schedules and therapeutic outcomes.

Species election

This application contains claims directed to the following patentably distinct species:
This application contains claims directed to the following patentably distinct species:

Claim 22(Group I) and claim 23 (Group VII) are directed to the patentably distinct species, i.e., diseases from cancer to cardiovascular disease.

The species are independent or distinct because diseases/disorders recited in claims 22-23, e.g., cardiovascular disease, urological disease, hematological disease, respiratory disease, gastroenterological disease and cancer have distinct/different patient populations, treatment schedules as well as therapeutic outcomes.

Because these species are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for the species election and for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jon Weber, can be reached on (571) 272-0925. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

/Samuel W Liu/
Examiner, Art Unit 1656
March 10, 2009

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657